REMARKS

This Amendment is being submitted in response to the Office Action dated June 4, 2009 in the above-identified application. Concurrently with this Amendment, Applicant submits an RCE and a petition for a five-month extension of time for filing an Appeal Brief, based on a Notice of Appeal filed by Applicant on November 20, 2009, along with the requisite fees and the authorization to charge our Deposit Account 50-0552 for any fee deficiencies. The time for filing an Appeal Brief is thereby extended to June 20, 2010.

Claim 4 has been amended to indicate in the body of the claim that "said GHS-R antagonist lowers the blood glucose level in the patient". Claims 4 and 10 are pending in the case. Claims 1 to 3, 5 to 9 and 11 to 13 were previously canceled without prejudice. No new matter has been introduced by the amendments.

In view of the amendments made herein and the remarks below, Applicants respectfully request reconsideration and withdrawal of the rejections and objections set forth in the June 4, 2009 Office Action.

REJECTIONS UNDER 35 USC § 102

Claims 4 and 10 were rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2001/0020012 A1).

Claim 4, as amended reads:

> A method of lowering the blood glucose level which comprises administering an effective dose of a growth hormone secretagogue receptor (GHS-R) antagonist to a patient with diabetes mellitus, wherein said GHS-R antagonist is selected from the group consisting of a ghrelin analog antagonist, [D-Lys-3]-GHRP-6 and [D-Arg-1, D-Phe-5, D-Trp-7, 9, Leu-11] substance P, and wherein said GHS-R antagonist lowers the blood glucose level in the patient.

Claim 4 is directed to a method of lowering blood glucose level. The Anderson publication does not teach a method of lowering blood glucose level. Indeed, there is no mention at all in the Anderson publication of blood glucose level, let alone a method of lowering it. Instead, the Anderson publication is directed only to treatment for the regulation of food intake. Therefore, one of skill in the art would have no reason to look to the Anderson patent and it cannot anticipate the present claims.

In the Office Action at page 4, the Examiner found Applicant's argument of against inherency non persuasive because the recitation "...lowering the blood glucose level..." was not given patentable weight because the recitation occurs in the preamble." This recitation has now been added to the body of the claim and therefore should be accorded patentable weight. As a result, claim 4 is not anticipated by the Anderson publication.

The Examiner also argues that the Anderson publication anticipates the claimed invention by "teaching a method for treatment of Type II diabetes (page 1, paragraph [0013] with the antagonist for the receptor GHS-R 1A (page 2, paragraph [0022]) which a ghrelin analog antagonist [sic]." The Examiner has improperly read these paragraphs outside the context of the remainder of the Anderson publication. The Anderson publication generally mentions treatment of various diseases requiring regulation of food intake, such as obesity, type II diabetes, anorexia and lack of appetite in children with a growth hormone deficiency. However, the patent does not teach use of a GHS-R 1A **antagonist** for treatment of these diseases. Review of the claims of the Anderson publication is instructive in this regard and are therefore set forth below:

> 1. The use of a compound that is a ligand for the receptor GHS-R 1A, or pharmaceutically acceptable salts thereof, for the manufacture of a medicament for the regulation of food intake.
>
> 2. The use according to claim 1, wherein the compound does not induce a therapeutic effective growth hormone release at the therapeutic dose of the compound.

3. The use according to claims 1 or 2, wherein the medicament is for humans.

4. The use according to any one of claims 1-3, wherein the medicament is a non-injectable medicament.

5. The use according to any one of claims 1-4, wherein the ligand is an agonist.

6. The use according to any one of claims 1-4, wherein the ligand is an antagonist.

7. The use according to any one of claims 1-5, wherein the compound is selected from the group consisting of adenosine, ghrelin and ghrelin homologues.

8. A method for the regulation of food intake, which method comprises administering an effective amount of a compound as defined in any one of claims 1, 2 or 5-7 to a patient in need of such a treatment.

9. A method for identifying compounds for the regulation of food intake, characterized by screening out compounds that act as ligands for the GHS receptor type 1A (GHS-R 1A).

10. Compounds identified by a method according to claim 9.

11. The use of a compound as defined in any one of claims 1, 2 or 5-7 for the manufacture of a medicament for the regulation of Body Mass Index (BMI).

12. The use of a compound as defined in any one of claims 1, 2 or 5-7 for the manufacture of a medicament for the treatment of anorexia.

13. The use of a compound as defined in any one of claims 1, 2 or 5-7 for the manufacture of a medicament for the treatment of lack of appetite in children with a growth hormone deficiency.

14. The use of a compound as defined in any one of claims 1, 2 or 5-7 for the manufacture of a medicament for the treatment of obesity.

15. The use of a compound as defined in any one of claims 1, 2 or 5-7 for the manufacture of a medicament for the treatment of Type II diabetes.

16. The use of a compound according to any one of claims 1,2 or 5-7 for the manufacture of a medicament for the treatment of wasting associated with AIDS.

17. A pharmaceutical composition comprising, as an active ingredient, a compound as defined in any one of claims 1, 2 or 5-7 or a pharmaceutically acceptable salt thereof together with a pharmaceutically acceptable carrier or diluent.

18. A composition according to claim 17 in unit dosage form, comprising from about 0.05 to about 2000 mg, preferably from about 0.1 to about 500 mg of a compound as defined in any one of claims 1, 2 or 5-7 or a pharmaceutically acceptable salt thereof.

19. A pharmaceutical composition for the regulation of food intake, the composition comprising, as an active ingredient, a compound as defined in any one of claims 1, 2 or 5-7 or a pharmaceutically acceptable salt thereof together with a pharmaceutically acceptable carrier or diluent.

20. A pharmaceutical composition according to any one of the claims 17-19 for oral, nasal, transdermal, pulmonal or parenteral administration.

Claim 5 calls for a ligand for the receptor GHS-R 1A that is an agonist. Claim 6 calls for a ligand for the receptor GHS-R 1A that is an antagonist. Claim 15, which is for use of a compound for the manufacture of a medicament for the treatment of Type II diabetes (and indeed, all of the claims directed to treatment of diseases) depend from claims 1, 2 or 5-7 and thus, specifically exclude claim 6, the antagonist claim. Thus, the Anderson publication teaches use of a GHS-R 1A agonist for the treatment of Type II diabetes, and, if anything, teaches away from the use of a GHS-R 1A antagonist for the treatment of Type II diabetes.

Applicants also point out that it is not appropriate for the Examiner to claim inherency for a GHS-R 1A antagonist based on a teaching for a GHS-R 1 A agonist. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by person of ordinary skill. As stated in *In re Oelrich:*

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. See *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981)

Therefore, in order to conclude by the logic of inherency that GHS-R antagonist lowers blood glucose level based on the disclosure of Anderson, the Examiner is required to show that one of ordinary skill in the art who reads the Anderson publication will recognizes that GHS-R antagonist lowers blood glucose level. The Examiner cannot meet this burden, as the Anderson only teaches the use of a GHS-R 1 A agonist for Type II diabetes.

Applicant's also refer the Examiner's attention to Forest v. Ivax and Cipla; CAFe Docket No.2007w 1059 wherein the Federal Circuit affirmed the district court finding that claim 1 of United States Reissue Patent 34,712 was not anticipated because it does not disclose "substantially pure" escitalopram as claimed in claim I and it therefore would not enable a person having ordinary skill in the art to obtain that compound. *Forest Labs. v. Ivax Pharms. and Cipla*, No. 2007-1059 (Fed. Cir. 2007). The cited reference predicted that one citalopram enantiomer would be more potent as a serotonin reuptake inhibitor than another. In affirming the District Court, the Federal Circuit stated:

> Because a racemate does encompass its two enantiomers, it in effect does state that there is a (+)-enantiomer of citalopram, but it does not tell how to obtain it. A reference that is not enabling is not anticipating. *Elan Phann., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003). The Smith reference, as a

> pharmacology paper, thus does not enable the preparation of the (+) enantiomer of citalooram . ....., we see no error in the finding that the Smith reference does not enable one of ordinary skill to make (-I-)-citalopram and hence that the Smith reference does not anticipate claims to (+)-citalopram.

Similarly, the Andersen publication merely confirms in Examples 3-5 that administration of the compounds (adenosine, NN703, NNC26-1187, NNC26-129l and ghrelin), all of which are recognized to be GHS-R agonists, stimulate feeding. Thus, the examples of Anderson show that GHS-R agonists stimulate feeding. It cannot be concluded from this disclosure that the Andersen publication provides any enabling disclosure that a GHS-R antagonist would be effective in the treatment of Type II diabetes.

Further, adenosine, which is described in Examples 2 and 3 of Andersen, is not even a GHS-R agonist. For support on this point, Applicant's enclose a Harmansson, N-O., Adenosine is not a direct GHSR agonist – artificial cross-talk between GHSR and adenosine receptor pathways, Acta Physiol, 190 (2008), pp. 77-86 and refer the Examiner's attention to the abstract contained therein. As such, the Andersen publication cannot provide an enabling disclosure even for GHS-R agonists and certainly does not provide an enabling for GHS-R antagonists. For this additional reason, the Anderson publication cannot anticipate the presently claimed invention which is directed to a method of lowering a blood glucose level by administering a GHS-R antagonist.

CONCLUSION

In view of the amendments set forth herein and remarks above, Applicants respectfully submit that the pending claims are allowable, and solicit the issuance of a notice to such effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number provided.

Respectfully submitted,

DAVIDSON, DAVIDSON & KAPPEL, LLC

By: _____

Leslye B. Davidson
Reg. No. 38,854

DAVIDSON, DAVIDSON & KAPPEL, LLC
485 Seventh Avenue, 14th Floor
New York, New York 10018
(212) 736-1940